UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,221	08/04/2003	Peter D. Roberts	LSBC-0137-CP04B	1497

27860 7590 02/27/2007

LARGE SCALE BIOLOGY CORPORATION
3333 VACA VALLEY PARKWAY
SUITE 1000
VACAVILLE, CA 95688

EXAMINER	
ZHENG, LI	
ART UNIT	PAPER NUMBER
1638	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/634,221	ROBERTS ET AL.	
	Examiner	Art Unit	
	Li Zheng	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3-25,27-29 and 31-37* is/are pending in the application.

4a) Of the above claim(s) *4,5,28,29,31,33-35 and 37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3,6-25,27,32 and 36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 12/2006
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 3, 6-25, 27, 32 and 36 in the reply filed on 11/16/2006 is acknowledged.

The requirement is deemed proper and is therefore made FINAL.

Specification

2. The status of the U.S. application recited on page 23, line 1 needs to be updated.

Claim Objections

3. Claims 3 and 14 are objected to for the following reasons:

In claim 3: the recitation – a – should be inserted in line 2 and line 5 before "modified".

In claim 14: the recitation, "aDEAD", should be changed to – a DEAD --.

4. Claims 6, 7, 12, 20, 22, 32 and 36 are objected to because they depend on non-elected claim 4.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 6-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 6, 7, 20, and 22: the recitation, "the foreign RNA" or "said foreign RNA", renders the claim indefinite. It is unclear it refers to the first foreign RNA or the second foreign RNA. The metes and bounds are not clear.

6. Claims 3, 6-25, 27, 32 and 36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

A review of the full content of the specification indicates that identifying 16 kDa cysteine-rich protein of RNA-1 is essential to the operation of the claimed invention.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a

precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." (See *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997)). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id. Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." Id.

A review of the language of claims indicates that claims are broadly drawn to a genus of genes encoding 16 kDa cysteine-rich protein of RNA-1 of tobravirus. However, the only tobravirus that comprises a sequence encoding a 16 kDa cysteine-rich protein is TRV. The specification does not describes any other tobravirus cysteine-rich protein that has a size of 16 kDa. The genus Tobravirus comprises only 2 other viruses, pea early browning virus and pepper ringspot virus. The corresponding cysteine-rich protein of these other two viruses is 12 kDa (McFarlane, S.A., J. Gen. Virol., 1999, 80:2799-2807, see page 2800). It is suggested that "16 kDa" be removed from claim 3. Therefore, given the breadth of the claims and the lack of enough description of claimed genus, a person skilled in the art would conclude that applicants are not in possession of the claimed invention.

7. Claims 13-14, and 16-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a bipartite RNA viral vector, which comprises any modified tobravirus RNA-1 comprising a first foreign RNA sequence encoding all or part of putrescine N-methyltransferase, wherein said first foreign RNA sequence is operably linked to the 3' end of the stop codon of the RNA sequence that encodes for a 16 kDa cysteine-rich protein of RNA-1, and any modified tobravirus RNA-2 comprising a promoter-gene construct comprising a subgenomic promoter operably linked to a second foreign RNA sequence encoding all or part of putrescine N-methyltransferase, wherein said promoter-gene construct is inserted in place of the 2C gene, does not reasonably provide enablement for said bipartite RNA viral vector wherein the first and second foreign RNA sequence encode all or part of any Nop 10-like small nucleolar ribonucleoprotein, any DEAD box RNA helicase, any methionine synthase, any PRP 19-like splicesomal protein, any CRS2 protein, or any GTP-binding protein, instead of putrescine N-methyltransferase. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The specification teaches that plants transfected with a vector expressing a sequence encoding Nop 10-like ribonucleoprotein showed increased stem circumference, distorted leaves and severely stunted growth. The specification also indicates that the increase in stem circumference may be a desired trait for the forest industry (page 57, lines 5-14). However, the term "may" indicates that it was not known if such a plant would be desirable by the forest industry, as it is also severely stunted. It

is apparent that further basic research is required to determine how the phenotype of increased stem circumference can be used in a plant that is also severely stunted for growth.

Further, the specification teaches that plants transfected with a vector expressing a sequence encoding DEAD box RNA helicase were stunted and had necrotic leaves (page 58, lines 8-9). However, the specification does not provide any guidance on either how to use such transgenic plants, or other uses of the claimed vector.

Still further, the specification teaches that plants transfected with a vector expressing a sequence encoding methionine synthase were stunted and had chlorotic and necrotic leaves (page 59, lines 13-16). However, the specification does not provide any guidance on either how to use such transgenic plants, or other uses of the claimed vector.

Furthermore, the specification teaches that plants transfected with a vector expressing a sequence encoding PRP 19-like splicesomal protein or GTP binding protein were also extremely stunted (page 44, lines 5-6; page 60, lines 3-4). Again, the specification does not provide any guidance on either how to use such transgenic plants, or other uses of the claimed vector. Further, there are numerous GTP-binding proteins, which do not all have the same biological functions. The specification does not provide any guidance on how to use the viral vectors expressing RNAs encoding various GTP-binding proteins as well as the corresponding transgenic plants.

Finally, the specification teaches that plants comprising the claimed vector in which CRS2 expression is inhibited have white bleached leaves. CRS2 is involved in

splicing the chloroplast group II intron (page 60, lines 17-22). The specification does not teach how to make use of the claimed vector to produce plants that comprise chloroplast that expresses improperly processed gene products.

See *Genentech Inc. v. Novo Nordisk,* A/S (CA FC) 42 USPQ2d 1001 (Fed. Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

In summary, given the breadth of the claims, lack of further guidance and additional working examples, and unpredictability of the art, undue experimentation would be required for a person skilled in the art to use claimed vector or transgenic plants expressing said vector.

Double Patenting

8. The examiner notes that the current invention group elected belongs to invention group II of the parent U.S. Patent Application No. 09/771,035, now U.S. Patent No. 6,700,040. Therefore an obvious-type of double patenting rejection over said patent is not applied.

Conclusion

Claims 3, 6-25, 27, 32 and 36 are rejected.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Zheng whose telephone number is 571-272-8031. The examiner can normally be reached on Monday through Friday 9:00 AM - 6:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ELIZABETH MCELWAIN
PRIMARY EXAMINER